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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/910,432	WAUGH ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Although the claims have multiple nested species and are indefinite such that it is unclear how many different inventions are claimed, the inventions have been restricted as well as possible in view of their indefiniteness.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-18 and 20--27, drawn to compositions comprising a non-covalent association complex comprising a positively charged backbone, classified for example in class 514, subclass 1.

II. Claims 28-37, drawn to methods of delivering a biological agent to a cell, classified for example in class 514, subclass 44.

III. Claims 38 and 39, drawn to a kit and a method of preparing a pharmaceutical composition, classified for example in class 514, subclass 2.

Group 1 comprises a variety of patentably distinct inventions that are linked by claims 1 and 19. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 19. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if

any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 1 and 19 are drawn to compositions comprising a positively charged backbone. The backbone may comprise one of three patentably distinct positively charged branching groups comprising the sequences:

1. $G_{n1}R_{n2}$ with n1 = an integer from about 0 to about 20, and n2 = an odd integer from about 5-25,

2. G_p-RGRDDRRQRRR-G_q,

3. G_p-YGRKKRRQRRR- G_q,

wherein the subscripts p and q are each independently an integer of from 0 to 20, or

4. any positively charged fragment of HIV TAT that is not listed in 1, 2 or 3 above, wherein each non-identical fragment represents a patentably distinct positively charged branching group.

The inventions are distinct, each from the other because of the following reasons:

Groups 1 and 2 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case biological agents can be delivered to cells using materially different compositions. For example, a nucleic acid can be delivered to a cell using either the claimed invention or a cationic liposome which is distinct from the claimed invention.

Groups 1 and 3 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the claimed composition need not be a therapeutic composition, so the claimed method does not necessarily produce the claimed compositions.

Groups 2 and 3 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation, functions, and effects because they use different steps to achieve different ends, i.e. delivery of a biological agent, and production of a pharmaceutical composition.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend

from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention. For example, claim 1 is drawn to :

A composition comprising a non-covalent association complex of: a) a positively-charged backbone; and b) at least two members selected from the group consisting of:

i) a first negatively-charged backbone having a plurality of attached imaging moieties;

ii) a second negatively-charged backbone having a plurality of attached targeting agents;

iii) at least one member selected from the group consisting of RNA, DNA, ribozymes, modified oligonucleotides and cDNA encoding a selected transgene;

iv) DNA encoding at least one persistence factor; and

v) a third negatively-charged backbone having a plurality of attached biological agents;

wherein said association complex carries a net positive charge and at least one of said two members from group b) is selected from groups i), iii) or v).

As an example of the indefiniteness of the claim, note that item 'v' is drawn to a third negatively charged backbone, however, it is unclear whether or not this requires that there must also be a first and a second negatively charged

backbone, i.e. one can only have item 'v' in a composition if at least two of items 'i', 'ii' or iii' (all drawn to negatively charged backbones) are in the composition. If Applicant intends that one can have item 'v' in the composition without at least two other negatively charged backbones, then such embodiments would lack proper antecedent basis for "a third negatively charged backbone. Furthermore, it is unclear if a composition comprising DNA comprising a targeting agent could satisfy simultaneously both items ii and iii. In other words would a composition comprising a positively charged backbone and double stranded DNA comprising a targeting agent anticipate species ii/iii, or would another negatively charged backbone be required? In any event, the claim has been interpreted to embrace 24 different species of non-covalent association complexes including those comprising the following combinations of group members: i/ii; i/iii, i/iv; i/v; ii/iii; ii/v; iii/iv; iii/v; iv/v; i/ii/iii; i/ii/iv; i/ii/v; i/iii/iv; i/iii/v; i/iv/v; ii/iii/iv; ii/iii/v; i/iv/v; iii/iv/v; i/ii/iii/iv; i/ii/iii/v, i/ii/iv/v; ii/iii/iv/v; and i/ii/iii/iv/v. Each of these combinations is a different species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-5 and 10-39 generic.

Should Applicant elect a species comprising item 'iii' then Applicant must also elect a member, or a single combination of members, from the group consisting of RNA, DNA, ribozymes, modified oligonucleotides, and cDNA encoding a selected transgene

Applicant is also required to elect a therapeutic or cosmeceutical agent from the species set forth in the specification, i.e., lidocaine, Novocain,

bupivacaine, procaine, tetracaine, benzocaine, cocaine, mepivacaine, etidocaine, proparacaine ropivacaine, prilocaine, azelastine, ketotifen, traxanox, corticosteroids, cromolyn, nedocromil, albuterol, bitolterol mesylate, pirbuterol, salmeterol, terbutyline, theophylline, neomycin, streptomycin, chloramphenicol, norfloxacin, ciprofloxacin, trimethoprim, sulfamethyloxazole, the .beta.-lactam antibiotics, tetracycline, nefopam, oxypertine, imipramine, trazadone, biguanidines, sulfonylureas, chloropromazine, fluphenazine, perphenazine, proclorperazine, promethazine, thiethylperazine, trifluprομazine, haloperidol, scopolamine, diphenidol, trimethobenzamide, atracurium mivacurium, rocuronium, succinylcholine, doxacurium, tubocurarine, and botulinum toxin (BOTOX), amphotericin B, nystatin, candicidin, itraconazole, ketoconazole, miconazole, clotrimazole, fluconazole, ciclopirox, econazole, naftifine, terbinafine, griseofulvin, propanolol, propafenone, oxyprenolol, nifedipine, reserpine nitric oxide donors, cortisone, hydrocortisone, dexamethasone, prednisolone, prednisone, fluazacort, indomethacin, ibuprofen, ramifenizone, prioxicam, adriamycin, cyclophosphamide, actinomycin, bleomycin, duanorubicin, doxorubicin, epirubicin, mitomycin, rapamycin, methotrexate, fluorouracil, carboplatin, carmustine (BCNU), cisplatin, etoposide, interferons, phenesterine, taxol, camptothecin, vinblastine, vincristine, amantadine, methisazone, idoxuridine, cytarabine, acyclovir, famciclovir, ganciclovir, foscamet, sorivudine, trifluridine, valacyclovir, cidofovir, didanosine, stavudine, zalcitabine, zidovudine, ribavirin, rimantatine, dantrolene, diazepam, COX-2 inhibitors,progestogen, GPIIb/IIIa inhibitors, tissue plasminogen activators, streptokinase, urokinase,

heparin, thrombin, factor V, factor VII, factor VIII, insulin, growth hormone, prolactin, EGF (epidermal growth factor), cyclosporine, azathioprine, mizorobine, FK506, prednisone, VEGF (vascular endothelial growth factor) a VEGF blocker, vitamin A, vitamin D, vitamin E, or vitamin K. Currently claims 1, 2, 4, and 6-39 are generic.

Should Applicant elect group 3, a further election of species of routes of administration is required. Applicant must elect from intravenous, topical, intraperitoneal, subdermal, subcutaneous, transcutaneous, intramuscular, oral, intra-joint, parenteral, intranasal, and inhalation routes. Currently claims 28-31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 571-272-0564.

Richard Schnizer, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER